Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 24-27, 68-70, 77-80, 90-114 and 116-121, 124-133, and 136-140 are pending in the application, with claims 70, 90, 98, 106, 114, 121 and 133 being the independent claims. Support for the changes to claims 121 and 133 can be found, for example, in original claims 123 and 135 respectively. These changes are believed to introduce no new matter, and their entry is respectfully requested. In accordance with 37 C.F.R. § 1.116(b), these amendments are made to present the rejected claims in better form for consideration on appeal.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Rejections Under 35 U.S.C. § 101

Claims 90-114 and 116-140 were rejected under 35 U.S.C. § 101 for allegedly not being supported by an asserted specific, substantial or well established utility. Paper No. 17, page 2. This rejection was maintained despite Applicants' assertion of the specific and substantial usefulness of the claimed galectin 9 protein for diagnosing, *inter alia*, asthma and/or Hodgkin's disease. Moreover, Applicants have demonstrated the credibility of this assertion by showing that galectin 9 is highly homologous with ecalectin, a protein known to play a role in these diseases. *See* Amendment and Reply Under 37 C.F.R. § 1.111, pages 11-14.

A. Legal Standard for Satisfying Utility Under 35 U.S.C. § 101

The Federal Circuit has recently articulated the standard for utility:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. See *Brenner v. Manson,* 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.,* 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger,* 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention "is capable of serving any beneficial end").

Juicy Whip, Inc. v. Orange Bang Inc., 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999).

The M.P.E.P. also provides guidance to examiners when determining whether an application has met the utility requirements. In particular, utility under 35 U.S.C. § 101 is satisfied if (i) the claimed invention has a well established utility or (ii) the applicant has asserted for the claimed invention any specific and substantial utility that is credible. *See* M.P.E.P. (Eighth) § 2107 (II)(A) and (B) (2001).

B. Applicants Have Satisfied the Utility Requirement

The present application explicitly asserts several specific, substantial and credible uses for Galectin 9. Accordingly, Applicants respectfully assert that Galectin 9 certainly provides some identifiable benefit under *Juicy Whip*, and its utility is specific, substantial and credible under the PTO's guidelines.

1. The Specification Asserts At Least One Specific Utility

The M.P.E.P. provides guidance to examiners to determine whether a utility is specific. Specifically, it states that "[a] 'specific utility' is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class

of the invention." M.P.E.P. (Eighth) § 2107.01 (I) (Specific Utility) (2001) (emphasis in original). Thus, if a utility is not general, it must be specific.

Applicants respectfully emphasize that their specification does disclose at least one specific utility of the galectin 9 protein. Rather than indicating that galectin 9 may generally be useful for diagnosing diseases, Applicants point out that the specification teaches the use of galectin 9, *inter alia*, for diagnosing specific diseases including asthma and/or Hodgkin's disease. *See* Specification, page 29, lines 3-9.

These uses of galectin 9 are specific uses that are not applicable to a general class of compounds. *See Revised Interim Utility Guidelines Training Materials* (2001), *available at* http://www.uspto.gov/web/patents/guides.htm (last modified Sept. 13, 2001). The use of an uncharacterized protein as an amino acid source or a protein supplement are uses that apply to "virtually every member of a general class of materials such as proteins" and therefore are not specific utilities under the facts of example 4. *Id.* at 32-33. Applicants respectfully point out that not every protein is useful for diagnosing asthma and/or Hodgkin's disease. Thus, Applicants submit that the specification discloses at least one specific utility for the galectin 9 protein.

2. At Least One Asserted, Specific Utility Is Substantial

The M.P.E.P. also provides guidance to examiners in determining whether a specification discloses a substantial utility. In particular, "[a] 'substantial utility' defines a 'real world' use. . . . [A]ny reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." M.P.E.P. (Eighth) § 2107.01 (I) (Substantial Utility) (2001).

Applicants respectfully emphasize that the specification discloses at least one substantial use for the galectin 9 protein. Galectin 9 provides a public benefit, e.g., better diagnosis, *inter alia*, of asthma and/or Hodgkin's disease. Applicants respectfully urge the Examiner to regard these utilities as substantial.

3. At Least One Asserted Specific, Substantial Utility is Credible

The M.P.E.P. also provides guidance to examiners in determining whether a specification discloses a credible utility. In particular, it states that "[c]redibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., . . . printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement." M.P.E.P. (Eighth) § 2107 (II)(B)(1)(ii) (2001).

Applicants submit that at least one of the above asserted specific, substantial uses of galectin 9 protein is credible to a person of ordinary skill in the art. Further, Applicants have provided printed publications which exemplify the diagnosis of asthma and/or Hodgkin's disease as credible to one of ordinary skill in the art. Matsumoto *et al.* describe human ecalectin, a protein identical to Applicant's galectin 9 except for an additional 12 amino acids. *See* Amendment and Reply Under 37 C.F.R. § 1.111, pages 11-12 (June 16, 2001), and previously submitted Exhibit D cited therein. A recent publication has specifically indicated that ecalectin is involved in asthma. *See* Hirashima, M. "Ecalectin/Galectin-9, a Novel Eosinophil Chemoattractant: Its Function and Production," *Int. Arch. Allergy Immunol. 122*(suppl 1):6, 9 (2000) (provided as Exhibit I). Indeed, the Matsumoto reference discusses how ecalectin levels increase in

patients suffering from allergies when subjected to an allergen. Exhibit D, page 16978. Thus, a skilled artisan would recognize the relationship between ecalectin and asthma, a specific allergic disorder. This would lead the skilled artisan to deem as credible Applicants' assertion regarding the utility of galectin 9 for diagnosing asthma via antibody based techniques. Another recent publication also confirms ecalectin's involvement in Hodgkin's disease. *See* Hirashima, M. "Ecalectin as a T Cell-Derived Eosinophil Chemoattractant," *Int. Arch. Allergy Immunol. 120*(suppl 1):7, 9 (1999) (provided as Exhibit J). Thus, a skilled artisan would also recognize as credible Applicants' assertion that galectin 9 is useful for diagnosing Hodgkin's disease via antibody based techniques.

C. The Examiner Has Not Made a Prima Facie Showing of Lack of Utility

The M.P.E.P. provides guidance to examiners when making a rejection under 35 U.S.C. § 101 for lack of specific or substantial utility:

> Where the asserted utility is not specific or substantial, a *prima facie* showing **must** establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing **must** contain the following elements:
>
> (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;
>
> (ii) Support for factual findings relied upon in reaching this conclusion; and
>
> (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

M.P.E.P. (Eighth) § 2107 (II)(C)(1) (2001) (emphasis added).

The M.P.E.P. also provides guidance to examiners when making a rejection under 35 U.S.C. § 101 for lack of credible utility:

> Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility **must** establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing **must** contain the following elements:
>
> (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
>
> (ii) Support for factual findings relied upon in reaching this conclusion; and
>
> (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

M.P.E.P. (Eighth) § 2107 (II)(C)(2) (2001) (emphasis added).

The Examiner has failed to provide any evidence or sound scientific reasoning to establish that an artisan would reasonably doubt Applicants' assertion of specific, substantial and credible utility for galectin 9. Accordingly, Applicants respectfully assert that the Examiner has not satisfied all of the above elements and has not made a *prima facie* showing that the asserted utility is not specific, substantial and credible.

The Examiner's rejection of claims 90-114 and 116-140 under 35 U.S.C. § 101 is based on factors that are not a part of the above mentioned utility analysis. In particular, the Examiner found Applicants' assertion of a utility to be unpersuasive "as the instant specification makes no mention of the chemoattractant qualities of galectin-9." Paper No. 17, page 2. Further, the Examiner alleges that "detecting diseases such as asthma, allergic diseases, cancers including breast, ovary, prostate, bone, liver, lung, pancreas, spleen, melanoma, renal astrocytoma and Hodgkin's disease . . . are not

considered to be specific and substantial [utilities] because the specification fails to disclose any particular function beyond the binding of galactose or the biological significance of the instant galectin-9 protein . . . ." Paper No. 17, page 3.

Biological or chemical explanations of how or why galectin 9 plays a role in asthma and/or Hodgkin's disease are not necessary to support utility. Rather, "as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use." M.P.E.P. (Eighth) § 2107.03 (I) (2001) (*citing Nelson v. Bowler,* 206 U.S.P.Q. 881, 884 (CCPA 1980)). Here, Applicants have shown by documenting with the above mentioned publications that the activity of galectin 9 is implicated in asthma and/or Hodgkin's disease. Moreover, this activity is reasonably correlated to the assertion that galectin 9 is useful to raise antibodies with which to diagnose these diseases.

The Examiner also bases her rejection by alleging that the specification at page 25, line 22 to page 27, line 18 "discusses only general properties of antigenic epitopes." Paper No. 17, page 3. However, the Examiner mistakenly refers to the incorrect section of the specification. Applicants actually referred to page 29, lines 3-9 of the specification (and not page 25, line 22 to page 27, line 18) to point out their assertion of a specific, substantial and credible utility. *See* Amendment and Reply Under 37 C.F.R. § 1.111 at page 6, lines 15-20 (June 15, 2001).

The Examiner also states that "in the absence of any further objective data, the utilities recited . . . are prophetic." Paper No. 17, page 3. Applicants respectfully urge the Examiner that this is not a proper basis upon which to rest a utility rejection. It is immaterial whether the asserted utility is prophetic. As described above, 35 U.S.C.

§ 101 requires a specific, substantial and credible utility. Hence, a prophetic assertion of utility that is specific, substantial and credible meets the utility requirement under 35 U.S.C. § 101.

In view of the facts set out above, Applicants submit that a skilled artisan would not reasonably doubt that the claimed polypeptides can be useful, *inter alia*, in generating antibodies for purposes of diagnosing asthma and/or Hodgkin's disease. As such, Applicants assert that the presently claimed invention possesses a specific, substantial and credible utility that constitutes a patentable utility under 35 U.S.C. § 101. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

II. Rejections under 35 U.S.C. § 112

The Examiner has maintained her rejection of claims 90, 92, 94-98, 100, and 102-140 under 35 U.S.C. § 112. In particular, the Examiner states that the specification does not enable claims drawn to fragments of galectin 9, proteins comprising amino acid sequences 95% identical to galectin 9, or proteins encoded by polynucleotides that hybridize to the polynucleotide complement of the galectin 9 coding region of SEQ ID NO:3. The Examiner also appears to be maintaining her rejection under 35 U.S.C. § 112 on the grounds of the above mentioned rejection under 35 U.S.C. § 101. Applicants respectfully traverse both of these rejections.

A. §112 Rejections Based on §101 Rejections

The Examiner has also used the 35 U.S.C. §101 utility rejection (*supra*) as the basis of a 35 U.S.C. §112 enablement rejections with respect to claims 90, 92, 94-98,

100, and 102-121, 124-133, and 136-140. For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. (Eighth) § 2107(IV) at 2100-36 (2001). Therefore, since the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejection of claims under 35 U.S.C. § 112, first paragraph, based on lack of utility of the claimed invention, should be withdrawn. Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112 as it applies to claims 90, 92, 94-98, 100, and 102-121, 124-133, and 136-140.

B. §112 Enablement Rejections

Applicants respectfully assert that their specification is enabling as to a specific, substantial and credible use of galectin 9 fragments, sequences that are 95% identical to galectin 9, and proteins encoded by nucleotides that hybridize to the antisense strand of SEQ ID NO:3. As described above, galectin 9 is useful, for example, for raising antibodies to diagnose patients for asthma and/or Hodgkin's disease. The Specification at page 26, lines 20-28 expressly identifies the epitopic regions of galectin 9 believed to be useful for raising antibodies. In particular, amino acids 62-102, 226-259 and 197-308 are epitopic regions expected to be useful for raising antibodies. The Specification at page 29, lines 20-27 also provides specific antibody based techniques with which to diagnose asthma and/or Hodgkin's disease. Accordingly, a person of ordinary skill in the art would recognize that protein sequences with these epitopic regions largely intact could be used for raising antibodies. Furthermore, Applicants have previously provided

evidence that as few as 6 contiguous amino acids in an epitopic region suffices for purposes of raising antibodies. Amendment and Reply Under 37 C.F.R. § 1.111, page 13 and Exhibit G.

Independent claims 90 and 98 and their respective dependent claims 92, 94-97, 102-105, 128 and 129 are explicitly drawn to proteins that are at least 95% identical to galectin 9. Because the galectin 9 protein is 311 amino acids long, these claims only encompass proteins that differ from galectin 9 by no more than 15 amino acids. Any of the epitopic regions disclosed for galectin 9 could be preserved even if as many as 15 amino acids were altered. Hence, the skilled artisan would know to leave at least one of the epitopic regions largely intact for purposes of raising antibodies, for example, to diagnose asthma and/or Hodgkin's disease. Thus, the specification is enabling for proteins that are at least 95% identical to galectin 9.

Independent claim 106 and its dependent claims 107-113 and 130 are explicitly drawn to protein fragments containing at least one of the epitopic regions. Just as these epitopic regions in galectin 9 are useful for raising antibodies for diagnostic purposes, protein fragments containing these epitopic regions are also useful for raising antibodies. Because a person of ordinary skill in the art would recognize this utility, the specification is enabling for an isolated protein comprising an amino acid sequence consisting of at least one of the recited epitopic regions.

Independent claims 114 and 121 and their respective dependent claims 116-120, 124-127, 131 and 132 are drawn to protein fragments of galectin 9. The skilled artisan would recognize that a protein fragment with one of the epitopic regions largely intact is

useful for raising antibodies. Thus, the specification is enabling for protein fragments of galectin 9.

Independent claim 133 and its dependent claims 136-140 are drawn to a protein encoded by a nucleotide that hybridizes to the antisense strand of SEQ ID NO:3. The skilled artisan would recognize that such a nucleotide encodes for a protein that maintains largely intact at least one of the epitopic regions. Thus, the specification is enabling for such a protein.

Because the Specification enables a use of claims 90, 92, 94-98, 100, and 102-121, 124-133, and 136-140, Applicants respectfully urge the Examiner to reconsider and withdraw the § 112 enablement rejection as it has been applied to these claims.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Claim 121. (amended) An isolated protein comprising a fragment of the amino acid sequence of SEQ ID NO:4;

wherein said protein [has an activity selected from the group consisting of:

(a) lactose binding activity; and

(b) binding activity for an antibody having specificity for] specifically binds an antibody that specifically binds a protein consisting of the complete amino acid sequence of SEQ ID NO:4.

Claim 133. (twice amended) An isolated protein comprising amino acid residues encoded by a polynucleotide which hybridizes to the polynucleotide complement of the coding region of SEQ ID NO:3 under the following conditions:

(a) incubating overnight at 42°C in a solution consisting of 50% formamide, 5x SSC, 50 mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 μg/ml denatured, sheared salmon sperm DNA; and

(b) washing at 65°C in a solution consisting of 0.1x SSC;

wherein said polynucleotide encodes a protein [having a biological activity selected from the group consisting of:

(a) lactose binding activity; and

(b) binding activity for an antibody having specificity for] that specifically binds an antibody that specifically binds a polypeptide consisting of the complete amino acid sequence of SEQ ID NO:4.

Claims 122, 123, 134 and 135 were cancelled.